Response/Arguments

This amendment is submitted responsive to the final office action mailed on August 21, 2009, having a shortened statutory period of November 21, 2009, with a Request for Continued Examination (RCE) under 37 CFR §1.114. Claims 123–155 are pending in the application and have been finally rejected.

With this response, claims 123, 124, 126–129, 131, 133, 135–137, 139, 141, 145, 146, 148, and 152–155 have been amended. Claims 129, 130, 132, 134, 147, and 149–151 have been cancelled. New claims 156 – 161 have been added. Support for the amended claims and the added claims can be found in paragraphs [0042], [0046], [0164], [0175], [0198], [258], [0271] and [0275] of the published application having the publication number 2007/0161885. Claims 123–129, 131, 133, 135–146, 148, and 152–161 remain in the application.

Claim Rejections – 35 U.S.C. §102

Claims 123-125, 128-136, 138-139, 142-143, 144-151 and 155 are rejected under 35 U.S.C. §102(b) as being anticipated by Kimchy et al. (US 2003/0139661; hereinafter Kimchy '661).

Claim 123, as amended herein, recites an apparatus for detecting clinically-relevant features of a gastrointestinal (GI) tract of a subject, with a capsule, adapted to be swallowed by a subject, wherein the capsule includes at least one radiation source emitting X-ray or gamma radiation having an energy of at least 10 keV and at least one radiation detector detecting radiation produced in response to the emitted radiation, wherein the at least one radiation detector detects first radiation having an energy in a first energy window corresponding to Compton-backscattered radiation and concurrently therewith detects radiation having a second energy in a second energy window corresponding to X-ray fluorescence (XRF) radiation from an X-ray contrast agent composition. The X-ray contrast agent composition is introduced in the GI tract and consists essentially of a stable, non-radioactive isotope. The capsule also includes a control unit which analyzes signals from the concurrently detected Compton-

backscattered radiation and the XRF radiation and to generate information useful for identifying a clinically-relevant feature of the GI tract of the subject.

Kimchy '661 discloses, *inter alia*, an ingestible device 12, arranged for imaging nuclear radiation of a radiopharmaceutical. A radiopharmaceutical is defined as a substance which actively emits radiation in an energy range that includes alpha, beta, gamma and x-ray radiation. The emission is based primarily on the radioactive decay of unstable isotope, such as I^{123}, I^{131}, to name just a few.

In contrast to Kimchy '661, the present invention employs a radiation source emitting X-ray or gamma radiation having an energy of at least 10 keV, wherein the radiation source is disposed in the capsule. The contrast agent swallowed by the subject introduced in the GI tract consists essentially of a *stable, non-radioactive isotope* which by definition does not emit X-ray or gamma radiation. The detected radiation is therefore, unlike the radiation in Kimchy '661, not produced by the radiopharmaceutical agent administered to the patient, for example introduced in the GI tract, but rather by the Compton-backscattered radiation and the XRF radiation, both of which are caused by, or excited by, the X-ray or gamma radiation emitted by the source.

Although Kimchy '661 mentions that a light-emitting source could be incorporated in the capsule, the light-emitting source in Kimchy '661 does not have the same features as the source disclosed in the present application and does not cooperate with the detector in the same manner as claimed in claims 123, 155 and 160. For example, Kimchy '661 discloses as radiation sources a laser light source (paragraphs [0102], [0110]), an ultrasound probe (paragraph [0133]), and an MRI probe (paragraph [0138]). Paragraph [0081] in the present application refers to emitters and sensors mentioned in the prior-art patent document US 6,324,418 to Crowley et al., which is directed to a portable tissue spectroscopy apparatus and a capsule. Crowley, like Kimchy '661, discloses only the spectroscopic investigation of light impinging *directly* on the tissue in order to distinguish, for example, between normal and cancerous tissue. In other words, although mentioning x-ray "radiation sources," Kimchy '661 does not disclose a radiation detector detecting first radiation having energy in a first energy window

corresponding to Compton-backscattered radiation and concurrently therewith detecting second radiation having energy in a second energy window corresponding to X-ray fluorescence (XRF) radiation from an X-ray contrast agent composition consisting essentially of a stable, non-radioactive isotope, as now recited in claim 123, as well as in claims 155 and 160.

Moreover, Kimchy '661 also does not disclose a control unit which analyzes signals from the concurrently detected Compton-backscattered radiation and the XRF radiation and generates information useful for identifying a clinically-relevant feature of the GI tract of the subject.

Applicant therefore respectfully submits that the independent claims 123, 155 and 160 are not anticipated by Kimchy '661 and are hence patentable.

Claim Rejections – 35 U.S.C. §103

Claims 126–127 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kimchy '661 in view of Sato (EP 0390478 A1).

Claim 126 recites collimating the radiation *source*, whereas claim 127 recites collimating the radiation *detector*. Regarding claim 127, applicant failed to find any disclosure in Sato suggesting a collimated detector, which may be desirable in the context of the present invention for accepting Compton-backscattered radiation only within a certain angle. Sato discloses an X-ray apparatus for measuring thickness of a film on the sample based on the intensity of the induced fluorescent X-ray from the sample. As stated in col. 1, lines 7–19, the fluorescent X-ray film thickness measurement apparatus employs the collimator 5 to collimate a primary X-ray 4 emitted from an X-ray spherical tube so as to produce a beam spot of a predetermined diameter and then to direct the X-ray onto the sample 7 through a mirror 6 which is used in observation of the sample. The collimator collimates a primary X-ray so as to direct an X-ray spot of sub-millimeter size onto the film on the object (col. 1, lines 43–45). However, Sato does not disclose or suggest a radiation detector with at least one collimator for detecting collimated radiation. Regarding claim 126, Sato's published

application, while disclosing collimation of an x-ray *source*, does not disclose the features lacking in Kimchy '661, so that Kimchy '661 and Sato, taken either alone or in combination, do not render claims 126 and 127 obvious.

Claims 137 and 140-141 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kimchy '661 in view of Gazdzinski (US 2001/0051766).

Gazdzinski discloses an endoscopic smart probe, and more particularly in paragraph [0051], an improved apparatus and method for delivery of a radionuclide to diseased tissue within the intestinal tract of a living subject. The source can comprise a gamma, beta, alpha, and/or even neutron emitting material which is shielded by a retractable shield. Gazdzinski also discloses an actuatable shield for blocking the radiation from the source. However, Gazdzinski does not disclose detecting radiation produced in response to the radiation emitted from the source, as recited in claims 123, 155 and 160.

Claims 152-153 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kimchy '661 in view of Kim et al. (US 6,719,684).

Kim discloses a micro-capsule type robot having a camera for examining the internal organs of a human body. However, Kim fails to disclose emission or detection of radiation and other features recited in the independent claims and not disclosed in Kimchy '661.

Claim 154 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kimchy '661, in view of Kim et al. (US 6,719,684) and further in view of Park et al. (US 2001/0038831).

Park fails to disclose emission or detection of radiation and other features recited in the independent claims and not disclosed in Kimchy '661.

Applicant therefore respectfully submits that the features of amended claims 123 and 155, as well as of new claim 161, are not disclosed or reasonably suggested by Kimchy '661 and the other references of record, taken either alone or in combination,

and are therefore patentable. The retained dependent claims 123–129, 131, 133, 135–146, 148, 152–154, 156–158, which depend from claim 123, and claims 159–160, which depend from claim 155, are then also patentable for at least the reasons that claims 123 and 155 are patentable.

Withdrawal of all rejections and allowance of the pending claims are respectfully requested.

/wolfgang e. stutius/ Date: 2009-12-08

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